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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,470	10/16/2003	Warren Stern	SOHN-P01-001	8880

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EXAMINER	
SCHLIENTZ, NATHAN W	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,470	STERN, WARREN	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11 and 18* is/are pending in the application.

4a) Of the above claim(s) *7 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8,9,11 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1, 5-11 and 18 are pending and claims 7 and 10 are withdrawn from consideration as being drawn to a non-elected invention. As a result, claims 1, 5, 6, 8, 9, 11 and 18 are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (WO 03/097011 A1) in view of Morgan (US 5,407,953).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Barth et al. teach a method of treating OSAS or obstructive sleep apnea (OSA), which is caused by a complete and/or partial obstruction of the patient's airway (a.k.a. obstructive hypopnea) (page 8, lines 9-14) by administering a therapeutically effective amount of at least one proton pump inhibitor, such as rabeprazole, omeprazole, lansoprazole (Prevacid™), esomeprazole, pantoprazole, leminoprazole, timoprazole, tenatoprazole, disulprazole, and the like (page 13, lines 20-23; page 19, lines 8-16; page 27, lines 32-35; page 28, lines 4-7).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Barth et al. do not teach treating a patient suffering from partial nocturnal upper airway obstruction which does not result in hypoxemia. However, Morgan teaches treating sleep apnea, hypopnea and/or snoring in a human patient (Abstract). Morgan further teaches that nasopharynx obstruction is the apparent cause of obstructive sleep apnea and snoring (col. 3, ln. 24-29). Therefore, Morgan differentiates between hypopnea and snoring (i.e., snoring does not result in hypoxemia as discussed by

Applicants Remarks filed 20 October 2008) and further provides motivation for treating hypopnea and/or snoring with the same medication.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to administer rabeprazole, omeprazole, lansoprazole (Prevacid™), esomeprazole, pantoprazole, leminoprazole, timoprazole, tenatoprazole, disulprazole, and the like, as taught by Barth et al., for the treatment of snoring, because Barth et al. teach these drugs for the treatment of hypopnea and Morgan teach treating apnea, hypopnea and/or snoring with the same medicament.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 3-4 that pilocarpine is effective against glaucoma because it causes "localized therapeutic response of contraction of the smooth muscle of the iris sphincter and of the ciliary muscle". Morgan states that “the stimulatory effect of pilocarpine upon the localized smooth muscles of the nasopharynx and hypopharynx results in an alleviation of the nasopharyngeal obstruction that is the apparent cause of obstructive sleep apnea and primary snoring”. Applicants argue that Morgan never

establishes any general connection between apnea/hypopnea treatment and primary snoring treatment, thus one cannot draw the conclusion that primary snoring can always or generally be treated the same way one treats apnea/hypopnea. Applicants argue that Morgan suggests pilocarpine may not be effective against central apnea, because the mechanism of central apnea involves interruption of diaphragmatic motion.

However, as pointed out by Applicants on pg. 3, ln. 13-16, Morgan teaches that the apparent cause of obstructive sleep apnea and snoring is the same, nasopharyngeal obstruction. Thus, a drug that is used to treat nasopharyngeal obstruction could be used to treat both obstructive sleep apnea and snoring. Therefore, one of ordinary skill in the art would have a reasonable expectation of success in treating snoring with a drug that has been shown to treat obstructive sleep apnea because they are both apparently caused by nasopharyngeal obstruction. Barth et al. teach treating obstructive sleep apnea (OSA) by administering a therapeutically effective amount of at least one proton pump inhibitor, such as lansoprazole.

Applicants further argue on page 4 that there is no apparent reason why GERD medicines may act to relieve nasopharyngeal obstruction since they inhibit acid secretion and reflex in stomach. It is quite possible that they treat apnea/hypopnea through mechanisms entirely independent of relieving nasopharyngeal obstruction. However, the examiner respectfully argues that since Morgan teaches that the cause of obstructive sleep apnea is nasopharyngeal obstruction, a drug used to treat this condition would necessarily treat nasopharyngeal obstruction. Thus, a drug known to treat obstructive sleep apnea, and thus necessarily treats nasopharyngeal obstruction,

will also be beneficial in the treatment of snoring. Applicants point out an example wherein one common apnea/hypopnea treatment is a drug that helps patients stay awake during the day, which would not be beneficial in treating snoring. However, the examiner argues that this example is not directed to treatment of nasopharyngeal obstruction, which is apparently the cause of obstructive sleep apnea and snoring. Therefore, this example is not relevant to the rejection.

Therefore, one of ordinary skill in the art would have a reasonable expectation of success in treating snoring with lansoprazole since Barth et al. teach treating obstructive sleep apnea with lansoprazole and Morgan teaches that obstructive sleep apnea and snoring have the same cause, nasopharyngeal obstruction.

2. Claims 1, 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao et al. (Gastroenterology, 1998, 114(4), 336), in view of Morgan (US 5,407,953).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Xiao et al. teach treating 18 patients with OSAS who suffer from snoring, daytime sleepiness and acid reflux, heartburn and regurgitation, through administration of cisapride 10 mg tid combined with omeprazole 20 mg q12h (Subject and Methods). Xiao et al. further disclose that there is a significant association between GER and esophageal body pressure, apnea/hypopnea, gross body movement, swallow and arousal (Conclusions).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Xiao et al. do not teach treating a patient suffering from partial nocturnal upper airway obstruction which does not result in hypoxemia. However, Morgan teaches treating sleep apnea, hypopnea and/or snoring in a human patient (Abstract). Morgan further teaches that nasopharynx obstruction is the apparent cause of obstructive sleep apnea and snoring (col. 3, ln. 24-29). Therefore, Morgan differentiates between hypopnea and snoring (i.e., snoring does not result in hypoxemia as discussed by Applicants Remarks filed 20 October 2008) and further provides motivation for treating hypopnea and/or snoring with the same medication.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to administer cisapride and omeprazole, as taught by Xiao et al., for the treatment of snoring, which differs from apnea and hypopnea, because Xiao et al. teach the combination for the treatment of OSAS and Morgan teaches treating apnea, hypopnea and/or snoring with the same medicament.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments are the same as above and therefore the examiners comments above are incorporated herein by reference.

3. Claims 1, 5, 6, 8, 9, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao et al. (Gastroenterology, 1998, 114(4), 336), in view of Morgan (US 5,407,953) and Hunt (Archives of Internal Medicine, 1999, 159(7), 649-657).

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Xiao et al. and Morgan are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Xiao et al. and Morgan do not teach treating patients who snore (i.e., partial nocturnal upper airway obstruction) with lansoprazole. However, Hunt teaches that omeprazole, lansoprazole and pantoprazole are proton pump inhibitors (PPI's) that are effective in the treatment of GERD.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use lansoprazole in the place of omeprazole for the treatment of patients suffering from GERD and snoring, as reasonably taught by Xiao et al. One of

ordinary skill in the art would have been motivated to treat a patient suffering from partial nocturnal upper airway obstruction (i.e., snoring or hypopnea) with the PPI's because Xiao et al. teach that there is a significant relationship between GERD and hypopnea, and GERD is known to be treated with PPI's such as omeprazole and lansoprazole, as reasonably taught by Hunt.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments are the same as above and therefore the examiners comments above are incorporated herein by reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616